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QW41/0625

EXAMINER	
LEWIS, A	
ART UNIT	PAPER NUMBER
37A1	

DATE MAILED:

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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/874,781	Applicant(s) BRUCE C. JOHNSON
	Examiner Aaron J. Lewis	Group Art Unit 3761

Responsive to communication(s) filed on 03/31/99 AMENDMENT

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 2-7, 16, 21, and 23-48 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 2-7, 16, 21, 23-34, and 36-48 is/are rejected.

Claim(s) 35 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2,6,23,27,47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an adhesively mounted [engaged] nasal dilator with a resilient member, does not reasonably provide enablement for a nasal dilator which “engages” a patient’s outer wall tissues by any means other than an adhesive. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of claims 2,6,23,27 and 47 due to the recitations of “...adapted to engage...” (claim2); and “...capable of engaging...” (claims 23,47) is not supported by the specification because 1. the phrases “...adapted to engage...” and “...capable of engaging...” do not positively define the dilator of the instant invention to be physically engaged with a patient’s outer wall tissues and 2. the metes and bounds of the phrases “...adapted to engage...” and “...capable of engaging...” include means other than the disclosed adhesive with which to “engage” a patient’s outer wall tissues. Additionally, specifically with respect to reason (1) above, a critical aspect of the nasal dilator of the instant invention REQUIRES it to be physically engaged with a patient’s outer wall tissues in order to actually dilate a patient’s nostrils; therefore, mere inferential recitations of

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“...adapted to engage...” and “...capable of engaging...” are neither consistent with nor supported by the disclosure of the instant application.

3. Claims 2,6,23,27 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A nasal dilator which is actually engaged with a patient’s outer wall tissues and which is engaged by means of an adhesive is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The scope of claims 2,6,23,27 and 47 due to the recitations of “...adapted to engage...” (claim2); and “...capable of engaging...” (claims 23,47) is not supported by the specification because 1. the phrases “...adapted to engage...” and “...capable of engaging...” do not positively define the dilator of the instant invention to be physically engaged with a patient’s outer wall tissues and 2. the metes and bounds of the phrases “...adapted to engage...” and “...capable of engaging...” include means other than the disclosed adhesive with which to “engage” a patient’s outer wall tissues. Additionally, specifically with respect to reason (1) above, a critical aspect of the nasal dilator of the instant invention REQUIRES it to be physically engaged with a patient’s outer wall tissues in order to actually dilate a patient’s nostrils; therefore, mere inferential recitations of “...adapted to engage...” and “...capable of engaging...” are neither consistent with nor supported by the disclosure of the instant application.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 2,3,23,27,47 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that these claims fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the original disclosure. In that paper, applicant has stated that the dilator 1. Must be physically engaged with a patient's outer wall tissues and 2. The means of engagement is limited to an adhesive, and this statement indicates that the invention is different from what is defined in the claim(s) because these claims lack any recitation of the nasal dilator of the instant invention actually being physically engaged with a patient's outer wall tissues and lacks any recitation of the means for engaging being through the incorporation of an adhesive.

6. Claims 2,6,23,27,46 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the actual positive recitation of the nasal dilator being engaged with a patient's outer wall tissues and an adhesive with which to accomplish the engagement.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 2-6,16,21,23,24,26,36,47 are rejected under 35 U.S.C. 102(b) as being anticipated by Iriarte (Spanish patent 289561), for the reasons set forth in the office action dated 10/28/98.

As to claims 2,3,23,26,36,47, the body (2) is readable upon the flexible truss and the elastic strip (1) is readable upon the resilient member. The body (2) and elastic strip (1) as illustrated in figs.2,3 include a segment devoid of adhesive and which bridges a patient's nose between opposed ends of the body which adhere to outer wall tissues of a patient's nostrils (fig.2D) which is readable upon an intermediate segment.

As to claims 4-6, Iriarte (figs.2D,3) illustrate the combination of a flexible strip having an adhesive substance located thereon with a resilient member (1) which is readable upon the at least one resilient band.

As to claim 16, Iriarte as discussed above, also discloses engagement means (i.e. adhesive on page 5, lines 9-14) in the form of adhesive.

As to claim 21, Iriarte, as discussed above, also discloses a pair of spaced apart end surfaces (fig.2D) of truss (2).

As to claim 24, figs. 2A-D and fig.3 of Iriarte illustrate a resilient band (1) oriented substantially parallel to a longitudinal extent of the truss (2).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 27-34,37-46,48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iriarte.

The difference between claim 28 and Iriarte is the shape of the intermediate section being narrower than the end sections of the nasal dilator.

While Iriarte illustrates intermediate sections which appear to be equal in dimensions (i.e. width) to the end sections, it is submitted that it would have been obvious to modify the shape of any section of the nasal dilator of Iriarte to be of any desired shape including an intermediate section having a more shallow/narrow shape/dimension than that of the end sections as an obvious matter of design choice with no new or unobvious results accruing.

As to claims 29,33, the resilient member (1) of Iriarte is placed adjacent a first side of the flexible strip of deformable material (2).

As to claims 27,30,34,37, while Iriarte discloses a singular resilient member (1), it would have been obvious to replicate the resilient member of Iriarte by mere duplication of an existing structural element. See *In re Harza*, 124 (USPQ) 378 (CCPA 1960); *St. Regis Paper Co., v. Benis Co., Inc.*, 193 USPW 8, 11 (7th Cir. 1977).

As to claims 31,32,38, Iriarte, page 5, lines 9-14 discloses that portion of the surface of the body (2) which extends beyond the area of the resilient member (1) includes an adhesive for engaging a patient's outer wall tissues. Figs.2A-D and fig.3 illustrate a substantial portion of that

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side of the body which engages a patient's outer wall tissues and readable upon the intermediate section as discussed above, being covered by resilient member (1); therefore, it would have been obvious that a substantial portion of the intermediate section is not adhesively engaged with a patient's outer wall tissues.

As to claims 39-46,48, while Iriarte is silent as to the composition of the material of the truss (1), it is submitted that it would have been obvious to make the truss of Iriarte of any well known material including plastic as an obvious matter of design choice with no new or unobvious results accruing.

11. Claims 7,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iriarte as applied to claims 27-34,37-46,48 above and further in view of Shippert ('402).

The difference between Iriarte and claim 7 is first and second release liners covering the adhesive substances on the first and second end regions of the flexible strip material.

Shippert, in an adhesively coated nose splint, teaches first and second release liners covering the adhesive substances on the first and second end regions of the flexible strip material for protecting the adhesive material prior to use.

It would have been obvious to modify the flexible strip of Iriarte to employ any well known means for protecting the adhesive material prior to application to a patient's nose including the use of first and second release liners covering the adhesive substances on any portion of the flexible strip including on the first and second end regions of the flexible strip material because it would have protected the adhesive prior to use as taught by Shippert.

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Claim 25 is substantially equivalent in scope and is included in Iriarte as modified by Shippert for the reasons set forth above with respect to claim 7.

Allowable Subject Matter

12. Claim 35 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments with respect to claims 2-7,16,21,23-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant adhesively mounted nasal coverings.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

June 21, 1999



Aaron J. Lewis
Primary Examiner